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IV

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/500,713	02/09/00	CONNOR	J 98-2046

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Thomas J Monahan
Intellectual Property Office
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EXAMINER

CHERNYSHEV, O

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/500,713

Applicant(s)

CONNOR ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 8 and 10 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of claims 1-10 in Paper No. 7 is acknowledged.

Claims 11-16 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 7.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

3. Claim 8 is objected to because of the following informalities: "florescent" should perhaps be spelled "fluorescent".

Claim 10 is objected to because of the following informalities: "wherein said measuring if performed" should perhaps be "wherein said measuring is performed". Appropriate correction is required.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Method for the detection of a demyelinating disease.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a detectable marker, which provides for measuring the extent of the binding. This ground of rejection could be obviated by incorporating elements of claim 7 into claim 1.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step where measuring the extent of binding of iron binding protein to the sample indicates the presence or absence of a demyelinating disease. The rejection could be avoided by including a method step, which explains the correlation between the results of binding measurement and detection of a demyelinating disease.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon (US Patent 4,813,399).

Gordon teaches a method for the treatment of neurological diseases with diagnostic applications using particles to affect myelin related diseases, i.e., the demyelinating diseases (see abstract, column 9 lines 30-36, claims 1, 36-38 and 41). The method disclosed by Gordon teaches using organic compounds, iron binding proteins ferritin and transferrin among them, for the process of direct contact with neurological tissue samples (neurological tissue in this case is defined as central and peripheral neurons and glial cells, which essentially constitute brain) followed by magnetic mapping of the results (see claims 46, 50 and 52). According to Gordon's invention, these compounds can be used as metal-organic compound complexes for the purpose of detection of binding sites (see claim 56), which meets the limitations of claim 7 of the instant application drawn to use of ferritin linked to a detectable marker.

8. Claim 3 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gordon (US Patent 4,813,399). Gordon teaches a method of diagnosis of demyelinating disease using direct contact of a tissue sample with an iron binding protein and subjecting such tissue to electromagnetic fields for magnetic mapping (see abstract, column 9 lines 30-36, claims 1, 46). Gordon does not teach brain tissue samples collected *via* surgical biopsy per se. However, it would appear this is the only reasonable way to obtain the tissue. Therefore, Gordon anticipates the claim 3. In the alternative, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to assume that since demyelinating diseases can only occur within neuronal tissue, which constitutes the brain, and that one of the most common practices to obtain a sample of the brain tissue is *via*

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surgical biopsy, and include brain tissue samples collected *via* surgical biopsy to successfully practice the invention of Gordon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 5, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US Patent 4,813,399). The teachings of Gordon are summarized above. Gordon teaches the use of ferritin to practice his invention. Gordon does not indicate the source of ferritin as being native or recombinant. However, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use native or recombinant or even organically synthesized for that purpose ferritin because the instant protocol does not indicate any limitations

or preferences of using any particular ferritin. Additionally, the skilled artisan would be motivated to use any readily available source of ferritin, which includes recombinant and native forms.

10. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon as applied to claims 1, 4 and 7 above, and further in view of Weng et al (US Patent 4,737,456). Invention of Gordon is summarized above. For the method of detection of ferritin binding sites Gordon uses electromagnetic field. Gordon does not teach radioisotopes or fluorescent dyes as detectable markers linked to ferritin, or autoradiography and immunofluorescent techniques for detection of iron binding protein binding sites. However, using fluorescent dyes or radioactive labels as detectable markers is very well established in the art, for example Weng et al. teach using such labels in ligand-receptor binding studies (see column 2 lines 10-25, column 3 lines 55-65 and claims 1, 2, 10, 12 and 13). It would have been *prima facie* obvious to a person of ordinary skill in the art to modify the iron binding protein of Gordon by labeling it with an autoradiographic or immunofluorescent marker, as it is shown by Weng et al. in order to attain the well known and widely disclosed advantage of being able to detect the product easily in assays.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Olga N. Chernyshev, Ph.D. *OC*
January 5, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud